Question: Do you know if these reporting requirements/decision trees are the same for all LPOs?

Answer: Unfortunately, no. The term for reporting SAEs differently on investigational and commercial treatment arms is 'differential reporting'. Not all LPOs use differential reporting. SWOG does use differential reporting in hopes that it will cause less work for you down the road. We don't want you to have to report every hospitalization for someone who is on standard-of-care treatment. However other groups have different approaches and possibly find that it is more consistent for their protocols to have a one-size-fits-all approach to SAE reporting. One thing currently in development, which will hopefully be available to sites within the next week, is a table that lets you know exactly where in the protocol you need to reference for SAE reporting.

Question: For attribution, if a patient got pneumonia possibly because they were on a chemo treatment that lowered immunity, would that be a possible attribution?

Answer: Yes, absolutely. If the patient already had lowered immunity coming into the trial from their previous regimen of treatment, and that contributed to pneumonia, that is definitely something you want to include in the report. You could enter it in the prior treatment section of the report or list it within section 7 as an other cause. The attribution would then be assigned in the report, as well.

Question: Would expectedness for death always be unexpected?

Answer: The expectedness for death will always be unexpected in the fact that it will require SAE reporting. Particularly for commercial treatments, you will notice that the table for SAE reporting doesn't differentiate between unexpected or expected death. So, even for commercial agents, if the patient died within 30 days of the last dose of protocol treatment, then it would require SAE reporting regardless of expectedness.

Question: How soon does an SAE need to be updated? If a patient is hospitalized, they may have fluctuations in labs, tachycardia on one of the days, etc. The reason I as is we have too much information.

Answer: There is no timeframe for updates. Use your best judgment in updating. We understand you may not receive records right away. Please create an amendment to the original report within a reasonable amount of time from when you receive the information.

There is a character limit within *CTEP-AERS Section 3: Describe the Event.* If you come across this situation where you have met the character limit and need to add additional information, please contact us and we will help remove some of the information that may not be quite as necessary to submit the report. There is never too much information unless you hit the character limit.

Question: If the patient is inpatient at the VA and we get labs done twice a day, are we required to report fluctuations?

Answer: No, please don’t report fluctuations. Our SWOG Physician Reviewer doesn't require this information to complete a review of the reports. I would suggest reporting what is relevant. Let us know the lowest/worst lab value and when the value returned to normal/resolved.